

Substitute for form 1449/PTO

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

Sheet	1	of	3
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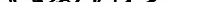
Application Number	10/705,996
Filing Date	11/13/2003
First Named Inventor	Platteeuw
Art Unit	
Examiner Name	
Attorney Docket Number	SYN-0053

## U. S. PATENT DOCUMENTS

[illegible]

**FOREIGN PATENT DOCUMENTS**

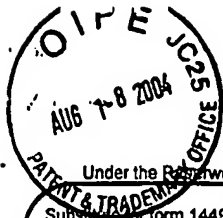
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>o</sup>
		Country Code <sup>3</sup> *Number <sup>4</sup> *Kind Code <sup>5</sup> (if known)				
KG		EP 0 034 432 B1	02-02-81	Imai et al.		
KG		EP 0 194 838 B1	09-06-93	Fukui et al		
KG		EP 0 533 297	11-19-97	Fukui et al.		

Examiner Signature		Date Considered	3-17-06
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Application Number 10/705,996

Filing Date 11/13/2003

First Named Inventor Platteeuw

Art Unit

Examiner Name

Sheet 2 of 3

Attorney Docket Number SYN-0053

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
KG		NDA 20-579, FDA Office of Clinical Pharmacology and Biopharmaceutics Review, pp 1-6, 1997	
KG		Flowmax, MIMMS Abbreviated Prescribing Information, MIMMS Australia, 1996-2002	

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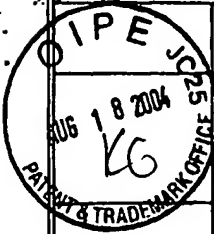

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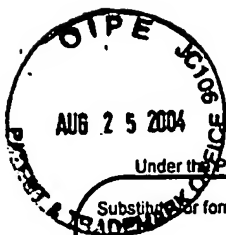
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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

	Presentation entitled: "In Vivo Performance of Hydrophilic Matrix Tablets Utilizing HPMC: Case Studies" by Tim D. Cabelka, Ph.D. and Thomas D. Reynolds, Ph.D., The Dow Chemical Company, October 17, 2000.
	FDA - FOIA Labeling Information for Flomax®, 2001
	Dunn CJ, Matheson A and Faulds DM. "Tamsulosin A review of its pharmacology and therapeutic efficacy in the management of lower urinary tract symptoms." <i>Drugs Aging</i> 2002; 19; 135-161.
	Dutkiewics S. "Efficacy and tolerability of drugs for treatment of benign prostatic hyperphasia." <i>Int Urology and Nephrology</i> 2001; 32; 423-432
	Harada K. and Fujimara A. "Clinical pharmacology of $\alpha_1$ selective and nonselective $\alpha_1$ -blockers." <i>BJU International</i> 2000; 86; 31-35
	Lyseng-Williamson KA, Jarvis B and Wagstaff AJ. "Tamsulosin An update of its role in the management of lower urinary tract symptoms." <i>Drugs</i> 2002; 62; 135-167
	Michel MC, Neumann HG, Mehlburger L, Schumacher H and Goepel M. "Does the time for administration (morning or evening) affect the tolerability or efficacy of tamsulosin?" <i>BJU International</i> 2001; 87; 31-34
	Soeishi Y, Korobi M, Kobayashi SI and Higuchi S. "Sensitive method for the determination of amsulosin in human plasma using high-performance liquid chromatography with fluorescence detection" <i>J of Chromatography</i> 1990; 553: 291-296
	Taguchi K, Schafers RF and Michel MC. "Radioreceptor assay analysis of tamsulosin and terazosin pharmacokinetics." <i>Br J Clin Pharmacol</i> 1998; 45: 49-55
KG	van Hoogdalem EJ, Soeishi Y, Matsushima H and Higuchi S. "Disposition of the selective $\alpha_1$ adrenoceptor antagonist tamsulosin in humans: Comparison with data from interspecies scaling." <i>J Pharm Sciences</i> 1997; 86: 1156-1161.
EXAMINER 	DATE CONSIDERED 3.17.06

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First Named Inventor Platteeuw

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
YG		RABASEDA and FITZPATRICK, "Tamsulosin: The First Prostate-Selective alpha 1a-Adrenoceptor Antagonist for Treatment of Symptomatic Benign Prostatic Hyperplasia," Drugs of Today, vol. 32, No. 3, 1996, pp 259-268	

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